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Report to the Secretary of Defense

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January 1987

MEDICAL READINESS

DOD Can Improve Management of Dated Drug Items Held as War Reserves

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ORIGINAL

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United States
General Accounting Office
Washington, D.C. 20548

National Security and
International Affairs Division

B-224081

January 9, 1987

The Honorable Caspar W. Weinberger
The Secretary of Defense

Dear Mr. Secretary:

The Department of Defense (DOD) is in the midst of a program to increase its medical readiness. This program includes a buildup of pre-positioned war-reserve (PWR) material to be stocked at or near the point of intended use. We have reviewed DOD's handling of dated medical supplies held as PWR, with special attention on DOD's implementation of several proposals that have been made to reduce the replacement costs.

Dated PWR medical supplies consist primarily of drugs but also include such items as X-ray film, bandages, and adhesives. These items are normally purchased with a requirement for a 3-year shelf life. When their shelf life expires, they must be replaced.

DOD's policy is that a 60-day supply of dated medical supplies should be stocked near the point of intended use. Replacement costs for dated items are directly related to the extent to which the services implement DOD's 60-day supply policy. The Air Force and the Marine Corps intend to comply with this policy. The Army and the Navy have, so far, limited their stocks of dated medical supplies to minimize replacement costs. However, the Navy intends to comply with the policy for some of its medical programs, and the Army is considering other stocking levels.

If all the services were to stock a 60-day supply, the total inventory value of dated items would probably exceed $390 million by the mid-1990s, with replacement costs of over $110 million annually if no cost-reduction efforts are implemented. Because the services have not stocked their full 60-day supply, replacement of dated items held as PWR cost about $9 million in fiscal year 1985. Although the services do not stock a 60-day supply, each service plans to increase the amount of its stock.

Proposals to Reduce Replacement Costs

Several proposals have been made for reducing replacement costs and making better use of dated medical supplies:

- Shelf life on some items can be extended. In order to determine which items have a longer shelf life than that now established, items need to be tested.
- DOD can buy items with a longer shelf life, though these items are generally more costly than those now bought.
- Manufacturers could stock a specified quantity of each item and deliver the item with a specified minimum shelf life remaining. Also, Defense Logistics Agency (DLA) depots could stock and rotate more items.

Evaluating and implementing the proposals require action by most of the agencies responsible for military medical supplies. Although the proposals have high potential for reducing costs, DOD has not formulated a plan to ensure that the proposals are evaluated and implemented in a systematic and timely manner. As a result, DOD's implementation of these proposals has been slow and piecemeal, though it has recently made more progress. DOD's actions on the proposals are summarized below. More details on our findings and scope and methodology are contained in appendix I.

Extension of Shelf Life

For years, DOD has periodically tested the stability of its military-unique items to see if their shelf lives can be extended. Through 1985, DOD's 14 military-unique items have been tested, primarily by the Food and Drug Administration, and all had their shelf lives extended. For example, one of the 14 items, with stock valued at $5.3 million, was determined to have a shelf life of 5 rather than 2 years.

In 1982, the Food and Drug Administration proposed that DLA's Defense Personnel Support Center award contracts to manufacturers to test the stability of commercial-type drug items. However, only one contract has been awarded for the testing of one drug. The item, with stock valued at $114,000, has had its shelf life extended by 2 years. The Support Center believes that additional staff are needed to evaluate all the potential items for shelf-life extension, but its request for five additional staff has not yet been approved by DLA Headquarters.

Buying Dated Items With Longer Shelf Life

Buying dated items with longer shelf lives would generally cost more initially but might save money in the long term. For example, in June 1983, the Support Center purchased tetracycline hydrochloride capsules

with a 10-year rather than a 5-year shelf life, resulting in an estimated savings of about $188,500 over a 10-year period. In December 1985, the Defense Medical Standardization Board approved nine other items to be procured with longer shelf lives.

Storing and Rotating Items by Manufacturers

As an alternative to the services stocking a 60-day supply of PWR, manufacturers would store and rotate dated items and DLA depots would increase their stockage levels. Manufacturers and depots would be required to keep a specified inventory of an item on hand and deliver the item where needed with a specified minimum shelf life remaining. Since 1982, the Support Center has been trying to award a stock-rotation contract but has been unable to do so because of legal and technical problems. However, the Center believes that it has overcome these problems and has scheduled a contract award for late 1986.

Conclusions and Recommendations

DOD's recent focus on medical readiness has increased attention on dated medical items that need to be prepositioned for use in the event of hostilities. If the services were to comply with DOD's 60-day supply policy, we estimate that, by the mid-1990s, without an ambitious program to implement cost-reduction proposals, over $110 million worth of items annually will have to be replaced because their shelf lives will have expired.

A number of proposals have been made to reduce the replacement costs of these items, but DOD's progress in implementing these proposals has been limited. Despite the upcoming growth in stocking and replacing dated PWR medical items and the apparent savings available by reducing the replacement rate and increasing the utilization rate, DOD has formulated no plan to ensure evaluation and implementation of the proposals in a timely manner. Unless it develops and implements such a plan, progress will continue to be limited.

Accordingly, we recommend that you direct that a plan of action be established to reduce the replacement costs of dated PWR medical items.

Agency Comments and Our Evaluation

DOD commented on a draft of this report and agreed with our findings and recommendations. (See app. II.) DOD stated that it would establish a formal plan by the fourth quarter of fiscal year 1987 to ensure evaluation and implementation of the proposals in a timely manner. DOD said that the plan will assign responsibilities, include proposed milestones,

and require continued analysis and evaluation of programs concerning the economic procurement and retention of dated medical supplies. However, DOD expressed concern that the annual replacement estimate of $110 million was overstated because the estimate assumes that the services will be fully funded in the outyears and will stock a 60-day supply of dated items which will be replaced when their shelf lives expire. Further, DOD expressed concern that the estimate does not consider reductions in replacement costs due to actions already taken or underway. Finally, DOD expressed concern that, although stock-rotation contracts have cost-reduction potential, the benefits do not accrue to PWR stocks in theatre.

In response, we would like to point out that the annual replacement estimate was developed from estimates provided to us by each of the services, using the assumptions noted by DOD. The estimate was intended to illustrate the potential largest magnitude of the replacement-cost problem. We agree that the $110 million represents the maximum cost.

We also agree that the benefits of stock-rotation contracts do not accrue to PWR stocks in theatre. However, such an approach may offer a cost-effective alternative for supplying some needed medical supplies because, although not stored in theatre, such stocks are readily available.

As you know, 31 U.S.C. 720 requires the head of a federal agency to submit a written statement on actions taken on our recommendations. This written statement must be submitted to the House Committee on Government Operations and the Senate Committee on Governmental Affairs not later than 60 days after the date of this report. A written statement must also be submitted to the House and Senate Committees on Appropriations with the agency's first request for appropriations made more than 60 days after the date of this report.

Copies of this report are being sent to the Chairmen, House and Senate Committees on Armed Forces and Appropriations; the House Committee on Government Operations; the Senate Committee on Governmental

Affairs; the Director, Office of Management and Budget; the Secretaries of the Army, Navy, and Air Force; the Director, DLA; and other interested parties.

Sincerely yours,

Frank C. Conahan

Frank C. Conahan
Assistant Comptroller General

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Abbreviations

DEPMEDS	Deployable Medical Systems
DLA	Defense Logistics Agency
DOD	Department of Defense
FDA	Food and Drug Administration
PWR	Prepositioned War Reserves

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DOD Implementation of Proposals to Lower Replacement Costs and Increase Utilization of Dated Medical Supplies

To maintain readiness for the outbreak of war, DOD prepositions medical supplies at or near the locations where war could occur. Some of these supplies (primarily drugs but also such items as X-ray film, bandages, and adhesives) have a limited shelf life and must be replaced about every 3 years.

In fiscal year 1985, DOD had prepositioned war-reserve (PWR) requirements for 728 different dated medical items, and replacement costs for the items on hand was $9 million. Because severe shortages of medical reserve material have existed since the end of the Vietnam War, DOD is now in the process of building up its PWR. Assuming that funding is available and the services are able to reach DOD's stocking goals, the total value of the PWR inventory of dated medical supplies could reach over $390 million by the mid-1990s, with an annual replacement cost of over $110 million.

Agencies Responsible for Military Medical Supplies

Several DOD agencies are responsible for managing military medical supplies. These agencies and their roles are as follows:

- The Assistant Secretary of Defense (Health Affairs) is the principal advisor to the Secretary of Defense for all health policies and activities. He oversees all health and medical resources and determines the priorities and resources required to meet DOD-wide health and medical programs.
- The Assistant Secretary of Defense (Acquisition and Logistics) is responsible for procurement and logistics policies, plans, and programs within DOD. In carrying out these functions, the Assistant Secretary coordinates with other officials within DOD, including the military services.
- The Surgeons General of the Army, the Air Force, and the Navy and the Commandant of the Marine Corps are responsible for establishing policies for acquiring and stocking medical material including war-reserve levels for their respective services.
- The Defense Medical Standardization Board, composed of medical representatives from each of the services, makes decisions about adding or deleting standardized items from DOD supply systems. It also serves as the single point of contact for professional and technical matters regarding medical material, and standardizes medical material for the military services, dealing with both war reserves and peacetime operating stocks. The Board reviews specifications for medical material to determine conformity with standards.

- The Defense Logistics Agency (DLA) Defense Personnel Support Center buys both peacetime and war-reserve medical material for the services and acts as the Standardization Board's agent in writing the specifications for medical material.
- DLA depots stock and issue medical material.

The Food and Drug Administration (FDA) also plays a major role in how DOD manages dated medical material. FDA approves the expiration dates (and any extensions of those dates) for dated medical items. These dates are based on test data from manufacturers.

Growing Medical-Material Replacement Costs

DOD's policy is that the military services should preposition a 60-day supply of medical war-reserve material at or near the points of intended use. The Air Force and the Marine Corps intend to comply with DOD policy. During fiscal year 1985, these two services experienced losses of $3 million and $5.5 million, respectively, of dated items whose shelf life had expired. The Army and the Navy have, so far, limited the amount of dated medical supplies stocked to minimize replacement costs. The Army is reconsidering its position and plans to stock more dated items, but it has not decided how much more. The Navy plans to stock a 60-day supply for its fleet-hospital program but limit its stock for the remainder of its PWR requirements.

Each of the military services developed the following data for us on requirements and potential replacement costs for PWR dated items. Their data was based on the assumption that they would stock a 60-day supply. However, the data has gaps. For instance, the Army did not estimate its total replacement costs. Also, the estimates do not consider reductions in replacement costs due to actions already taken or underway. We are presenting the services' data here to illustrate the approximate magnitude of the replacement-cost problem.

Air Force

Air Force policy is to buy and preposition a 60-day supply of dated medical items and to dispose of expired items. Thus, the $3 million in fiscal year 1985. Air Force PWR programs could contain $75.7 million worth of dated items in the 1990s. As this stockage level is achieved, replacement costs could increase each year, reaching $30 million a year in the mid-1990s.

Marine Corps

Marine Corps policy is to stock between 30 and 60 days of dated items, but it intends to change its policy to require a full 60-day supply. In 1985, Marine Corps losses of dated items were about $5.5 million, and losses in the 1990s are estimated at about $6.8 million annually.

Army

Army policy has been to buy and stock no more dated items than could be rotated with items used during peacetime. Much of its PWR dated stock is actually kept in DLA depots where it can be rotated to minimize losses. Currently, the Army—which breaks down its PWR requirements by theater—stocks only about 10 percent of its PWR overseas theater requirements of dated items, and 7 percent of its requirements for Army Reserve, National Guard, and other medical units which are maintained in the United States.

The Army is currently reviewing its stockage policy. Although it plans to buy and stock more dated items, it has not decided how much more. It is reviewing the feasibility of keeping a 30-day—rather than a 60-day—supply of PWR medical material for overseas theaters. Whether it decides to do so will depend on whether enough air transport will be available to get the material overseas in time of war and the projected amount of in-transit losses of dated items requiring special packaging or handling.

The Army's PWR requirements for dated medical items in the 1990s are about $229.7 million (for a 60-day supply), composed of overseas theater requirements of $158 million and Army Reserve, National Guard, and other requirements of about $71.7 million.

Because of the Army's unsettled PWR stockage policy, we did not obtain an overall estimate of replacement costs. The Army provided an analysis of its estimated replacement costs for the European theater, which has the largest single dated-item requirement—$84.2 million for a 60-day supply. Annual losses in the 1990s are projected at $35.9 million if full stockage levels are achieved for that theater in accordance with DOD policy. If the Army buys and stocks the balance of its total dated-item requirements of $145.5 million, replacement costs will increase by a comparable rate. Army Surgeon General officials say that a decision to keep a lower 30-day supply overseas would mean a net reduction of about 25 percent of theater medical PWR requirements, and a lower rate of losses.

In addition to its theatre requirements, the Army is stocking the dated medical material it will need for the deployable medical systems

(DEPMEDS) that it intends to preposition overseas.[1] Dated-item requirements for these systems amount to $46.3 million, with annual replacement costs of $20.5 million. An official of the Logistics Division of the Army Surgeon General's Office told us that the Army is studying the feasibility of including the DEPMEDS requirements as part of the total theater requirements, thus reducing total PWR requirements.

Navy

The Navy also limits its stockage of PWR dated items to minimize replacement costs. It segregates its requirements into those for fleet hospitals and those for other war-reserve programs.

For the fleet-hospital program, the Navy's dated item PWR requirements are $30.8 million, and the Navy estimates the annual replacement costs at $16.2 million. Navy officials informed us that they plan to stock a 60-day supply of dated items for this program and replace them when they expire.

For the remainder of its requirements (other fleet war-reserve programs), the Navy limits its stock to about 16 percent of its $10.6-million requirement. It keeps most of the stock in D'A depots so that it can be rotated with peacetime stock and used before its shelf life expires. A Navy official stated that the Navy does not plan to stock the full dated-item requirement for the other war-reserve programs but that, if the Navy did, annual replacement costs would be at least $2.5 million.

Table I.1 summarizes the PWR dated-item requirements by the mid-1990s for each of the services.

[1]DEPMEDS are the standardized, relocatable field hospitals which have from 60 to 1,000 beds and which the Army, Navy, and Air Force are now buying. (The Navy calls them "fleet hospitals.")

Table I.1: Cost of DOD's PWR Dated-Item Requirements and Estimated Annual Replacement Costs for the Mid-1990s

Dollars in millions

Military service	Cost of PWR dated-item requirements	Estimated annual replacement costs
Air Force:		
All war-reserve programs (60-day supply)	$75.7	$30.0
Marine Corps:		
Field medical support and maritime prepositioning ships (60-day supply)	N/A	6.8[a]
Army:		
Theater reserves (60-day supply)	229.7	35.9[b]
DEPMEDS (average of 10-day supply)	46.3[c]	20.5[c]
Navy:		
Fleet hospitals (60-day supply)	30.8	16.2
Other fleet war-reserve programs (60-day supply)	10.6	2.5
Total	**$393.1**	**111.9**

[a]Data on Marine Corps requirements was scattered at several locations, and we were unable to develop the data within a reasonable timeframe. Therefore, the estimated total DOD-requirement figure of $393.1 million is underestimated by whatever that amount might be. The estimated annual loss is based on funding requirements for replacing PWR dated items.

[b]The estimate is for the European theater only. The dated-item requirements for the theater are $84.2 million. Replacement costs would be lower if the Army reduced theater stockage levels to a 30-day supply.

[c]This estimate represents requirements and replacement costs for the systems to be prepositioned overseas or assigned to active medical units.

Proposals for Reducing Replacement Costs and Increasing Utilization

Over a period of years, several proposals have been made to reduce replacement costs and increase utilization of dated items. These proposals were made by various organizations, including the Standardization Board and FDA. The status of the proposals was summarized in a Standardization Board study (John Ferinde, Economic Procurement and Retention of Dated Medical Supplies, Jan. 1985). Evaluation and implementation of the proposals require action by most of the agencies responsible for military medical supplies. Although the proposals have high potential for reducing costs, DOD has not formulated a plan to ensure evaluation and implementation of the proposals in a systematic and timely manner. As a result, DOD's progress in implementing them has been slow and piecemeal, though it has very recently made more progress. The proposals are to

- extend shelf life through (1) DOD's testing of items in its

inventories and (2) manufacturers' testing of their products for possible extension of shelf life of these items as they pertain to future deliveries and inventories held by DOD activities;
- buy items with longer shelf life than that currently required; and
- increase rotational quantities of PWR dated stock through (1) contracts with suppliers to maintain and rotate inventories of dated items and (2) maximizing rotatable quantities of PWR stock in DLA depots.

Each proposal and actions taken to date are described below.

Extending the Shelf Life of Dated Items

The shelf life of some dated medical items could be extended by DOD's testing its inventories and through manufacturers' testing their products. Some limited testing has been done and has demonstrated that the replacement of dated items can be delayed.

DOD Testing of Inventories

For years, DOD has periodically tested the military-unique dated items in its inventory to determine whether their shelf lives could be extended. In 1976, the DLA's Defense Personnel Support Center became responsible for this program, and FDA now tests most of these items for the Support Center. Since the inception of the testing program through 1985, DOD's 14 military-unique items have been periodically tested with these results (the stock values are as of the time of the testing):

- 1 item with stocks valued at $12 million had its shelf life extended to 5 years;
- 2 items with stocks valued at $935,000 had their shelf lives extended to 20 years; and
- 11 items with stocks valued at $5.9 million had their shelf lives extended from between 4 and 30 years.

One example of the savings that can be achieved by extending shelf life is the testing of pralidoxime chloride injection, one of the items currently in the test program. At the time of purchase, this item had an estimated shelf life of 2 years. However, testing of inventory samples showed the item's shelf life to be 5 years. As a result, the shelf life for $5.3 million of stocks of the item in DLA depots was extended by 3 years.

Under another program, the Air Force in January 1986 agreed with the FDA to test 56 dated items prepositioned at Air Force activities in Europe. This testing covered items selected by the Air Force and was not limited to military-unique items. The current inventory value of the

items is $1.2 million, and the charge for testing them was $79,718. Recent test results showed that about 80 percent of the items could have their shelf lives extended, some up to 4 years. In June 1986, the program was extended to test inventories of the other services under the management of the Standardization Board.

Manufacturer's Tests

In 1982, an FDA official proposed that the Support Center award contracts to manufacturers to test the stability of three older lots of their product on an annual basis. Based on the test results, the shelf life of newer lots could be extended and that of older lots in DOD inventories could continually be extended until their potency fell below acceptable levels.

In July 1985, a contract was awarded for manufacturer testing. The contract required the manufacturer to make stability tests on the morphine sulfate injection for 3 consecutive years, at a cost of $795 per year or a total 3-year cost of $2,385. The initial test, in 1985, resulted in extending the shelf life of the item's inventory, valued at $114,000, by 2 years.

The Standardization Board study identified 20 drug items suitable for manufacturer testing, with shelf lives ranging from 18 to 60 months. The Army, Navy, and Air Force PWR requirements in the 1990s for these 20 items amount to about $80 million, with estimated annual replacement costs of about $15 million per year (based only on Army European theater and total Air Force projections).

The Support Center has stated that additional staff is needed in order to evaluate all the potential items for the manufacturers' expansion program. In March 1986, the Support Center requested DLA Headquarters to approve the addition of five people, including two pharmaceutical positions and one procurement position, for the purpose of implementing this program on a larger scale. A decision has not yet been made on this request.

Buying Dated Items With Longer Shelf Lives

In December 1985, the Standardization Board approved the extension of shelf life for nine items, which will enable the Support Center to procure them at the increased shelf life. According to the Standardization Board, the nine items are available for purchase at higher costs with shelf lives ranging from 4 to 5 years, rather than their current 3- and 4-year shelf lives. The value of the services' PWR requirements for the items is about

$23 million, with estimated annual replacement costs for the Army European theater and total Air Force of about $5.7 million.

In June 1983, the Support Center purchased 138,659 tetracycline hydrochloride capsules with a 10-year shelf life, although the item has usually been procured with a 5-year shelf life. The purchase was justified on the basis of a large war-reserve requirement for the item. We estimate that, since this was primarily procured for PWR, the savings on this procurement would be about $188,500 for the 10-year period. The savings are based on a per-capsule-cost difference of $.24 ($1.84 paid for the 10-year item versus $1.60 paid for the 5-year item purchased 2 months earlier), and the need for only one procurement of PWR rather than two.

Increasing Stock Rotational Capabilities

Another proposal is that dated items be stored and rotated by manufacturers of the items as well as by DLA depots. The plan as it relates to manufacturers is called the "industrial stock rotation program." It requires manufacturers to keep on hand a specified inventory of the item, and to deliver the item with a specified minimum remaining shelf life when requested by DOD.

We believe that further analysis is needed to establish the feasibility of having DLA and the manufacturers maintain and rotate dated items and to estimate savings. While both of these options could reduce losses due to shelf-life expiration, both have some disadvantages. For example, the price of the item might decrease over the contract period, and the item could be replaced. Also, since the stock would not be prepositioned, the services would have to arrange for delivery of the material to the point of use where and when it is needed.

Since 1982, the Support Center has been trying to award an industrial stock-rotation contract, but the first attempt to do so was unsuccessful. A review of the proposed award by the DLA Headquarters Procurement Policy Office found that it was deficient for a number of reasons:

- The use of a supply contract was inappropriate because DOD was principally buying a service rather than supplies.
- Though the contract was for 5 years, the multiyear contracting procedures under existing regulations were not followed.
- The basis for determining price reasonableness was not sound because the prices used were inappropriate; and estimating storage and handling costs, based on subsistence cold storage costs, was considered inappropriate for drug items.

In November 1985, the Support Center started the award process for another industrial rotation contract. The item selected was clindamycin phosphate injection. However, the Support Center later questioned this selection because it was available from only one manufacturer under a patent due to expire in January 1987.

In early 1986, the Support Center substituted sulfadiazine silver cream as the item for the rotation contract. The services' PWR requirements for sulfadiazine silver cream are about $2.9 million, with estimated annual replacement costs in the 1990s (Army European theater and total Air Force) of $850,000. The acquisition plan calls for

- a service contract for a 5-year period with an option for an additional 5-year period;
- separate pricing of the initial production costs of the item, warehousing costs, and rotation and handling costs;
- use of "should cost" analysis to establish price reasonableness; and
- a request to DLA headquarters for a deviation from the acquisition regulations to permit use of the 10-year contract period.

The Support Center solicited bids in July 1986 and scheduled a contract award for late 1986. Although we believe that this cost-saving proposal needs to be pursued, we have some serious doubts whether a multiyear contract is legal in this instance. This legal issue will be addressed in a subsequent letter to the Director, DLA.

The Standardization Board study identified a list of 33 additional dated items as candidates for the individual stock- rotation program. The military services' PWR requirements for the items are about $41 million, with annual replacement costs estimated to be $14.4 million in the 1990s. The other aspect of the proposal is to increase DLA stockage levels of dated items. Currently, both the Army and Navy maintain significant inventories of PWR dated items (valued at $14.6 million and $1.6 million, respectively) in DLA depots. Quantities are based upon the DLA's capability to rotate the items with peacetime stocks, thus avoiding losses due to shelf-life expiration. The Army has expressed an interest in stocking additional quantities of PWR dated items in DLA depots.

A Support Center representative told us that neither the Center nor DLA has made a study to determine the additional quantities of dated items that can be stocked and rotated in DLA depots. He stated that only limited space would be available for storage. He added that the Support

Center will consider requests by the services on an item-by-item basis to stock additional quantities of PWR material.

Other Proposals or Efforts Underway to Reduce Losses of Dated Items

Other approaches to cost savings have been suggested more recently, including

- a Standardization Board request to the Veterans Administration to participate in stock rotation for dated items, and
- an Air Force study to determine the feasibility of rotating dated items nearing expiration at war-reserve sites to peacetime Air Force activities that could use the items before they expire.

The potential savings of these proposals has not yet been determined. The Army Medical and Research Development Command has a project underway—a resuscitation fluids production system—which would significantly reduce stockage requirements for intravenous solutions, a dated item. Under this project, instead of stocking the intravenous solution, the services would stock only the systems to manufacturer the solution. The projected availability date for this system is between 1988 and 1990.

Objectives, Scope, and Methodology

The primary purpose of our review was to assess the merits of the proposals aimed at reducing the replacement rate of dated medical items and DOD's progress in evaluating and implementing them. We also looked into the extent to which the military services were implementing DOD's policy for stocking dated items in PWR. We examined the

- roles and responsibilities of the DOD activities involved in managing or acquiring medical material;
- merits of the proposals for reducing losses of dated items; and
- actions taken or planned to evaluate and implement the proposals.

During our review, we visited the following organizations:

- Surgeons General of the Army, Navy, and Air Force, and their field offices;
- Chief of Naval Operations;
- Marine Corps Headquarters;
- Naval Medical Command;
- Navy Fleet Program Office;

- DLA Headquarters and subordinate activities—the Defense Personnel Support Center and a defense depot;
- Defense Medical Standardization Board;
- Assistant Secretary of Defense (Health Affairs);
- Assistant Secretary of Defense (Acquisition and Logistics); and
- FDA.

At the Surgeons General offices and the other military service activities listed above, we obtained information through discussion and analyses of reports on

- expenditures for medical readiness and war reserves in the 1980s and early 1990s;
- policies on acquisition and stockage levels of PWR medical material, particularly the policies for acquiring and stocking dated items; and
- requirements for dated items, to the extent available, and current yearly losses of dated items due to shelf-life expiration and estimated losses in the 1990s.

At the Standardization Board, we discussed the merits and status of the proposals and actions taken to implement them. We also obtained and reviewed the Standardization Board study containing an analysis of the proposals and specific items that should be considered in evaluating and implementing the proposals.

Based on the items identified in the Standardization Board study and PWR requirements furnished by the services, we obtained and reviewed data to demonstrate the potential impact of the proposals if they were successfully implemented.

At the Support Center, we obtained and reviewed documentation in support of the savings reported under its program for testing military-unique drug items as well as other actions which resulted in savings of PWR dated items. We also discussed the merits of the proposals with Center officials and how implementation of them would affect the Center.

At the Defense Depot, Mechanicsburg, Pennsylvania, we reviewed and discussed depot procedures for issuing PWR stock to users.

We also discussed the merits of the proposals to extend shelf life with FDA officials.

We discussed the results of our review with officials of the Assistant Secretary Defense (Health Affairs), Surgeons General of the Army, Navy, and Air Force, Marine Corps, Headquarters, the Standardization Board, the Assistant Secretary of Defense (Acquisition and Logistics), the DLA activities, and the FDA.

Much of the data that the military services furnished us on PWR requirements and losses was computer-generated. We did not perform any tests to determine the accuracy or reliability of the data.

We performed our review mainly in fiscal year 1986, in accordance with generally accepted government auditing standards.

Comments From the Assistant Secretary of Defense (Health Affairs)

THE ASSISTANT SECRETARY OF DEFENSE

WASHINGTON, D.C. 20301-1200

HEALTH AFFAIRS

1986

Mr. Frank C. Conahan
Director, National Security and
International Affairs Division
United States General Accounting Office
441 G Street, N.W.
Washington, DC 20548

Dear Mr. Conahan:

This is the Department of Defense (DoD) response to the General Accounting Office (GAO) draft report "MEDICAL READINESS: DoD Can Improve Management of Dated Drug Items Held as War Reserves," dated September 23, 1986 (GAO Code 391555), OSD Case 7139.

The DoD concurs in the findings and recommendation contained in the draft report. In general, the DoD notes that the reported figures for annual replacement costs assume total loss of the forecasted prepositioned war reserve stocks. No allowance or offset for the impact of the various programs intended to reduce these projected losses is included. The enclosure provides comments in detail.

Sincerely,

for William Mayer, M.D.

Enclosure

GAO DRAFT REPORT DATED SEPTEMBER 23, 1986

(GAO CODE 391555)

DOD CAN IMPROVE MANAGEMENT OF DATED DRUG ITEMS HELD AS WAR RESERVES

DEPARTMENT OF DEFENSE COMMENTS

FINDINGS

FINDING A: Agencies Responsible For Military Medical Supplies. The GAO reported that to maintain readiness for war, the DoD prepositions medical supplies at or near possible war locations. The GAO noted that these supplies, known as prepositioned war reserves (PWR), have a limited shelf life and must be replaced about every 3 years. The GAO found that in FY 1985, the DoD had PWR requirements for 728 different medical item, and replacement costs for the items on hand was $9 million. The GAO found that several DoD organizations share responsibility for managing military medical supplies, including:

-- the Office of the Assistant Secretary of Defense (Health Affairs), which oversees all health and medical resources and determines the priorities required to meet DOD-wide health and medical programs;

-- the Office of the Assistant Secretary of Defense (Acquisition and Logistics), which is responsible for procurement and logistics policies, plans and programs within DOD;

-- the Surgeons General of the Army, Air Force, and Navy and the Commandant of the Marine Corps, who establish policies for acquiring and stocking these supplies, including the PWR levels for their respective Services;

-- the Defense Medical Standardization Board, which reviews and standardizes specifications for medical materiel;

-- the DLA Defense Personnel Support Center, which buys medical materiel for the Military Services; and

Now on pp. 8 and 9.

-- DLA depots, which stock and issue materiel. (pp. 3-4, pp. 7-8, Appendix I/GAO Draft Report)

DoD POSITION: CONCUR. The DoD agrees that it is necessary to maintain war reserve materiel at or near the point of its intended use. The intent of this policy is to sustain combat operations until resupply channels can provide the necessary wartime follow-on

ENCLOSURE

support. The DoD also agrees that there are, as identified, a number of agencies with responsibilities in the acquisition of medical supplies.

FINDING B: DoD Prepositioning Policy: Growing Medical Materiel Replacement Costs. The GAO observed that the recent DOD focus on medical readiness has increased attention to the fact that more dated medical items need to be prepositioned for use in the event of hostilities. The GAO reported that it is DoD policy for the Military Services to preposition a 60-day supply of medical materiel near intended use areas. The GAO observed that by the mid-1990s, these items will be valued at over $390 million, with replacement costs of over $110 million annually. The GAO found, for example, that to implement the 60-day policy for FY-1985, the Air Force and Marine Corps experienced losses of $3 million and $5.5 million, respectively, on dated items whose shelf life had expired. (The GAO noted that to minimize replacement costs, the Army and Navy have limited the amount of dated medical supplies stocked.) The GAO concluded that assuming the Services comply with the 60-day supply policy, without an ambitious program to implement cost reduction proposals, by the mid-1990s over $110 million worth of items will have to be replaced annually, because their shelf-life has expired (i.e., much greater than the $9 million replaced in 1985). In addition, the GAO concluded that even if the Services do not stock a full 60-day supply, they plan to increase the amount of materiel currently stocked. (pp. 1-4, pp. 8-13, Appendix I/GAO Draft Report)

Now on pp. 1-3 and pp. 9-12

DoD POSITION: CONCUR. The DoD agrees that there has been an intensified focus on medical readiness. This increased attention generates the potential for stocking greater quantities of PWR dated items. Some clarification is, however, needed with respect to replacement cost. The GAO observation of $110M for annual replacement is based on expiration and loss of the entire investment in PWR. Although the draft report states computations have been done, the GAO has not provided for the impact the various programs underway have on these costs. In addition, the GAO assumes a fully funded outyear program, which may or may not be the case. Finally, the GAO makes no mention that there are a number of shelf-life items included in the annual replacement requirement for which there is no known way to further reduce losses. Their shelf-life has already been extended and there is no peacetime use for the item; therefore, rotation to a wider consumption base is not available. Such items are already being purchased at the longest possible dating.

FINDING C: Proposals For Reducing Replacement Costs And Increasing Utilization. The GAO found that several proposals have been made by several organizations, such as the Standardization Board and the Federal Food and Drug Administration, to reduce replacement costs and increase utilization of dated items. The GAO reported that these proposals include:

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-- extending shelf life through (1) DoD's testing of items in its inventories and (2) manufacturers' testing of their products for possible extension of shelf life of these items as they pertain to future deliveries and of inventories held by DoD activities;

-- buying items with longer shelf life than that currently required; and

-- increasing rotational quantities of PWR dated stock through (1) contracts with suppliers to maintain and rotate inventories of dated item and (2) maximizing rotatable quantities of PWR stock in DLA depots.

In addition, the GAO found that other approaches to cost savings have been suggested, although not fully analyzed, which include:

-- a Standardization Board request to the Veterans Administration to participate in stock rotation for dated items; and

-- an Air Force Study to determine the feasibility of rotating dated items nearing expiration at war reserve sites to peacetime Air Force activities, so the items could be used before they expire.

The GAO concluded that although a number of proposals have been made to reduce the replacement costs of these items, the DoD has not formulated a plan to ensure evaluation and implementation of the proposals in a timely manner. The GAO also concluded that unless such a plan is developed, it appears progress in prepositioning medical supplies will continue on a limited scale. (pp. 2-4, pp. 14-20/Appendix I/GAO Draft Report)

Now on pp. 2-3 and pp. 12-17

DoD POSITION: CONCUR. The DoD agrees that the proposals listed originate with several organizations and that their implementation should mitigate the losses associated with stocking PWR. For the programs currently underway, the reduction will likely be substantial. For example:

(1) The Air Force shelf-life extension test completed in June 1986 resulted in approximately 80% of the items tested being extended. On the average, the Air Force gained 33 months of potency for stock with an average of 30 months of shelf-life. By 1990, this will result in an annual reduction of $3M in replacement costs for Air Force 500 Bed Assemblages. The shelf-life extension program has now been extended to all Services and it is being coordinated by the Defense Medical Standardization Board (DMSB). The DMSB staff anticipates final selection of the items to be made by November 1, 1986. Implementation of the program will continue with formal adoption of a Memorandum of Understanding to follow. Continued success, based on the Air Force experience with shelf-life extension, should produce substantial reductions in replacement costs.

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(2) Two current R&D programs, when implemented, will also have a substantial impact on reducing the requirement for some dated materiel. These are the Resuscitation Fluids Production and Reconstitution System (REFLUPS) and digital imaging systems. REFLUPS has the capability of nearly eliminating the requirement to stock shelf-life intravenous injection solutions and digital imaging systems will eliminate most x-ray film and film processing chemical requirements. Progress on both of these programs is being monitored by the DMSB.

(3) At this time, due to personnel resource constraints, the shelf-life expansion and the buy longer than normal dating programs have been stalled; however, the Defense Logistics Agency has made this a priority issue for resolution. The DMSB continues to evaluate shelf-life items included in PWR as new or replacement candidates for inclusion in these programs. Although the stock rotation contracts mentioned in the draft report also have cost reduction potential, the benefits do not accrue to stocks located in theater. By definition, prepositioning means at or near the point of intended use, although in some cases, such as medical, stocks labeled as PWR may be stored in DLA CONUS depots. Rotation of stocks held in Defense Logistics Agency, Veterans' Administration, and continental United States industry storage facilities may provide benefit towards reducing replacement costs, but not for prepositioned war reserve stocks held in the theater.

The programs currently underway represent more than limited scale progress. The DoD recognizes, however, that room for improvement exists.

RECOMMENDATION

Recommendation: The GAO recommended that the Secretary of Defense direct a plan of action be established to reduce the replacement costs of dated medical items for prepositioned war reserves PWR. (p. 5/GAO Draft Report)

Now on p. 3.

DoD POSITION: CONCUR. The Department of Defense agrees that a plan of action should be in effect to reduce the replacement costs of dated medical items held as prepositioned war reserves. The DoD will establish a formal plan by the fourth quarter of FY 1987 to ensure evaluation and implementation of the proposals in a timely manner. The plan will assign responsibilities, include proposed milestones, and require continued analysis and evaluation of all programs concerning the economic procurement and retention of dated medical supplies. Current actions, however, will not be held in abeyance. The DMSB will continue providing oversight, as well as technical expertise for their assigned responsibilities, and the contracting initiatives being conducted at the Defense Personnel Support Center, along with solving the personnel resource problem, will remain a priority for the Defense Logistics Agency.

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